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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/736,640	12/14/2000	Eric J. Panken	P-7443	8153

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MEDTRONIC, INC.
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EXAMINER

PAIK, SANG YEOP

ART UNIT	PAPER NUMBER
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3742

DATE MAILED: 12/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/736,640

Applicant(s)

PANKEN ET AL.

Examiner

Sang Y Paik

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 October 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, there is no proper antecedent basis for “the means for pacing”.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

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4. Claims 1-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Bennett et al (US 5,331,966).

Bennett et al discloses the claimed circuit having a means for detecting atrial depolarization signals by the subcutaneous electrodes on a hermetically sealed case, a means for pacing having at least one pacing lead into the right ventricle of a heart. Bennett further shows that the lead can be made from unipolar or bipolar leads.

5. Claims 1-5 are rejected under 35 U.S.C. 102(e) as being anticipated by Duffin (US 6,230,059).

Duffin discloses the claimed circuit having a means for detecting atrial depolarization signals by the subcutaneous electrodes on a hermetically sealed case, a means for pacing having at least one pacing lead into the ventricular chamber, and the lead made from unipolar or bipolar leads. (See Figure 2, and also see column 7, lines 5-49).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 6-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bennett et al (US 5,331,966) in view of Rapach et al (US 4,907,593) or Pless et al (US 5,489,293).

Bennett et al discloses all the structure including receiving ECG data, which includes the R-wave and P-wave signals detected from the from the SEA electrodes that are mechanically and electrically coupled to the ventricular chamber and disposed on the external portion of the

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medical device, and the external lead. Bennett et al, however, does not show having a digital to analog converter (DAC).

Rapach et al shows having a DAC for converting the digital signal to an analog signal to set the analog amplitude of the pulse output delivered to the lead in the heart. Pless et al also shows having a DAC in a ventricular pace unit to provide the regulated voltages to the lead in the heart.

In view of Rapach et al or Pless et al, it would have been obvious to one of ordinary skill in the art to adapt Bennett et al with the DAC unit to provide the analog signals to the lead in the art to trigger the desired stimulation..

8. Claims 12-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nigram et al (WO 00/61225) in view of Bennett et al (US 5,331,966) or Duffin (US 6,230,059).

Nigram et al shows the method of starting a PR cross check, discounting a p-wave, triggering a PVAPR interval when R-wave is detected, the PVAPR is used to blank p-waves and preventing PMT, and the VA interval extended by an AV interval is shown by the delay signal in Figure 2 with a p-wave being sensed after such interval. Nigram et al however does not show a pair of electrodes as the signal detector that is implemented by the software system.

Bennett et al or Duffin shows the software system using the digital processor to monitor the signals, and Bennett et al and Duffin further show that it is well known in the art to provide electrodes as the detector means to detect the ventricular signals in the heart. In view of Bennett et al or Duffin, it would have been obvious to one of ordinary skill in the art to adapt Nigram et al with the electrodes as the means to detect the ventricular signals since such electrode means provides an effective and convenient means to electrically detect and measure the conditions of

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the heart with the software system to conveniently monitor the signals and process the desired pacing signals.

Response to Arguments

9. Applicant's arguments filed 10/20/03 have been fully considered but they are not persuasive.

The applicant argues that Bennett does not exclusively detect P-waves with a SEA but seems to deal almost exclusively with recording in RAM portions of EGMs. This argument is not deemed persuasive since detecting P-wave and R-wave is well known when analyzing the PQRS electrogram (EGM) and Bennett implements the device to detect the EGM signals including P-waves. Furthermore, there is no claim recitation that the claimed device is used for detecting P-waves, exclusively. Duffin also implements its device to detect the EGM signals including the P-waves as well as R-waves.

With respect to Pless et al and Rapach et al, the applicant argues that there is no motivation to combine. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, they all involve in the same field of endeavor which is in the art of detecting and controlling the cardiac arrhythmias, and Pless et al and Rapach et al both teach applying the pulse in terms of voltage to stimulate and detect the cardiac

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signals necessary to determine its conditions. In view of such teaching, there is clear motivation to combine Pless et al and Rapach et al with the Bennett.

With respect to Nigam et al, it is noted that the pair of electrodes of SEA is taught by Bennett et al and Duffin and not by Nigam et al.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sang Y Paik whose telephone number is 703-308-1147. The examiner can normally be reached on M-F (8:00-5:30) First Friday Off.

The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0861.



Sang Y Paik
Primary Examiner
Art Unit 3742

syp